UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

April 8, 2002

MEMORANDUM

SUBJECT: **Chlorpropham (CIPC)** [018301], HED Response to CIPC Task Force Comments Dated March 27, 2002 on the Human Health Risk Assessment for the TRED. DP Barcode D282018 (No MRID).

From: Danette Drew, Chemist
Reregistration Branch 3
Health Effects Division [7509C]

Through: Steve Knizner, Branch Chief
Reregistration Branch 3
Health Effects Division [7509C]

To: Gary Mullins, Chemical Review Manager
Reregistration Branch 3
Special Review and Reregistration Division [7508C]

The Chlorpropham [CIPC] Task Force has submitted comments in a letter dated 3/27/02 in response to the error-only comment period for the "HED Human Health Risk Assessment Chapter for the Tolerance Reassessment Eligibility Decision"(D280134, 2/28/02, D.Drew). The Task Force represents producers Aceto Agricultural Chemicals Corporation and Cerexagri, Inc. HED has responded to those comments in this memorandum.

Task Force Comment:

While the Task Force did not have comments specific to the science findings of the TRED science chapters, they did request that language be included in the TRED and associated chapters regarding label application rates and supporting potato residue data. Specifically, they would like to have included a statement that positively indicates that residue data support current Task Force label rates and that use at the current label rates would not result in residues of chlorpropham on potatoes above the reassessed tolerance. The language suggested by the Task Force is as follows:

> *The Agency has reviewed all residue data submitted in conjunction with the RED and currently registered labels listed in Table 2 and has determined, based upon the application rates and timings listed, that resulting residue on potatoes in excess of the proposed tolerance of 30 ppm on whole tubers would not be exceeded.*

HED Response:

It was determined in the 1995 HED RED chapter and reiterated in the recent TRED chapter that *sufficient data are available to assess the adequacy of the established tolerance for potato. The data indicate that the tolerance may be reduced from 50 ppm to 30 ppm, provided the following application rates are not exceeded:*

> *aerosol fog at 0.022 lb ai/1000 lbs potato in each of two applications 90 days apart followed by direct spray at 0.0104 lb ai/1000 lbs potato; or*
>
> *aerosol fog at 0.033 lb ai/1000 lbs potato and a second aerosol fog 140 days later at 0.017 lb ai/1000 lb potato.*

These rates represent the maximum application rates, as well as the minimum retreatment intervals, used in the magnitude of the residue (Guideline 860.1500) studies submitted in support of the reregistration of chlorpropham. While the regimes listed above do not have to appear *verbatim* on the labels, the labels do have to specify a single and seasonal maximum application rate that is not in excess of those used in the residue studies. Also the labels must specify a retreatment interval reflecting the minimum intervals used in the residue studies.

HED has determined that the Task Force product label rates do not exceed the maximum *single* application rates used in the residue studies on potatoes. However, labels allowing more than one application do not specify a minimum retreatment interval. This is a deficiency. Additionally, labels do not clearly state the maximum application rate by specifying the maximum number of allowable applications. This is also a deficiency. The recommended CIPC product label amendments are detailed in a memorandum “Response to Registrant’s Letter dated November 20, 2001 Regarding Label Amendments” (D282154, 3/14/02, D. Drew; Attached). Without these amendments, HED cannot say with certainty that the maximum seasonal label rates do not exceed those rates used in the residue studies. Also there is no way to tell if actual retreatment intervals are greater or less than those of the residue studies. Therefore, HED is unable to

determine whether the residues resulting from application of CIPC according to current label directions would or would not be expected to exceed the reassessed tolerance. At this time, without the recommended label changes, it would not be appropriate to include a statement in the TRED indicating that the tolerance for CIPC on potatoes would not be exceeded based on current label directions.

cc: RF, List A file, D.Drew, Gary Mullins (SRRD), Cynthia Giles-Parker (RD).
RDI: S. Knizner 4/8/02
D.Drew: CM2, Rm 821E, 305-6028

ATTACHMENT

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

March 21, 2002

MEMORANDUM

SUBJECT: **Chlorpropham (CIPC)** [018301], Response to Registrant's Letter dated November 20, 2001 Regarding Label Amendments. DP Barcode D282154 (No MRID).

From: Danette Drew, Chemist
Reregistration Branch 3
Health Effects Division [7509C]

Through: Steve Knizner, Branch Chief
Reregistration Branch 3
Health Effects Division [7509C]

To: Cynthia Giles-Parker
Registration Division [7505C]

Executive Summary

Registration Division (RD) has requested that the Health Effects Division (HED) respond to a letter dated November 20, 2001 regarding *Label Amendments for Reregistration Per Chlorpropham RED* submitted on behalf of the Chlorpropham [CIPC] Task Force. The Task Force represents producers Aceto Agricultural Chemicals Corporation and Cerexagri, Inc. The letter discusses how residue data submitted by the Task Force support the application instructions appearing on the Task Force's currently registered CIPC labels. Although potato residue data support the standard application rates on the labels, the maximum allowable number of applications and minimum retreatment intervals are not clearly specified on the labels. HED recommends that label changes indicated in Table 1 should be made to all Task Force product labels. Labels for all other CIPC products should also reflect these changes.

Background

Chlorpropham (isopropyl *m*-chlorocarbanilate or CIPC) is a plant growth regulator used to inhibit sprout formation on stored potatoes. Chlorpropham is formulated as a ready-to-use product (RTU) or an emulsifiable concentrate (EC) by Aceto Agricultural Chemicals

Corporation, Cerexagri, Inc (a subsidiary of ATOFINA chemicals, formerly Alf Atochem), and Pin-Nip, Inc., the basic producers. Chlorpropham is applied as either an aerosol fogger to stored potatoes or as a direct (post-harvest) spray to potatoes.

The HED chapter of the Reregistration Eligibility Decision Document (HED RED) for Chlorpropham was issued in 1995 (K. Whitby, 1/19/95). An HED chapter of the Tolerance Reassessment Eligibility Document (TRED) was issued 2/28/02 (D280134, D. Drew). It was determined in the HED RED chapter and reiterated in the TRED chapter that *"sufficient data are available to assess the adequacy of the established tolerance for potato. The data indicate that the tolerance may be reduced from 50 ppm to 30 ppm, provided the following application rates are not exceeded:*

> *aerosol fog at 0.022 lb ai/1000 lbs potato in each of two applications 90 days apart followed by direct spray at 0.0104 lb ai/1000 lbs potato; or*
>
> *aerosol fog at 0.033 lb ai/1000 lbs potato and a second aerosol fog 140 days later at 0.017 lb ai/1000 lb potato.*"

These rates represent the maximum application rates, as well as the minimum retreatment intervals, used in the magnitude of the residue (Guideline 860.1500) studies submitted in support of the reregistration of chlorpropham.

Considerations and Conclusions

The 11/20/01 letter states that the Task Force's residue data support the currently registered labels for aerosol and spray application rates and scenarios, and that application rates used in the residue studies exceed those appearing on the labels. The labels specified in the letter are EPA Reg. Nos. 2749-70, 2749-264, 2792-40, 2792-41, 2792-69 and ID8300003. HED has examined these end-use labels, as well as other end-use labels registered by members of the Task Force (2749-517, 2749-519, 2749-520, 2792-70) and has determined that the label rates do not exceed the maximum single application rates used in the residue studies on potatoes. However, labels allowing more than one application do not specify a minimum retreatment interval. Additionally, labels should clearly state the maximum application rate by specifying the maximum number of allowable applications. Table 1 shows the product registration number, current label rates, and the recommended amendments for number of applications and retreatment intervals. The conclusions made herein also apply to the draft revised labels submitted in response to the chlorpropham RED.

Table 1. Summary of Current Task Force CIPC Labels and Recommended Amendments

EPA Reg. No.	Label Acceptance Date	Formulation Class	Product Name	Current Label "Standard"[1] Application Rate (ai)	Current Label Max. Seasonal Application (ai)	Current Label Max. Number of Applications	Current Label Retreatment Interval	Recommended Label Amendments
Aceto Agricultural Chemicals Corp.								
2749-517	5/25/95	7 lb/gal RTU	CIPC 7A	0.017 lb/1000 lb potato	NS [not specified] (0.025 lb/1000 lb potato implied)[2]	NS	NS	The highest recommended rate listed is "145%" of the "standard" rate. A retreatment interval is not specified. **Label should be amended to specify a minimum retreatment interval of 3 months (90 days). A maximum of two treatments should be specified.**[3]
2749-520	6/25/96	9.66 lb/gal RTU	CIPC 98A	0.017 lb/1000 lb potato	NS (0.028 lb/1000 lb potato implied)[2]	NS	NS	The highest recommended rate listed is "165%" of the "standard" rate. A retreatment interval is not specified. **Label should be amended to specify a minimum retreatment interval of 3 months (90 days). A maximum of two treatments should be specified.**[3]

EPA Reg. No.	Label Acceptance Date	Formulation Class	Product Name	Current Label "Standard"[1] Application Rate (ai)	Current Label Max. Seasonal Application (ai)	Current Label Max. Number of Applications	Current Label Retreatment Interval	Recommended Label Amendments
2749-70	9/5/85	3 lb/gal EC	Spud Nic-3	0.0104 lb/1000 lb potato	NS	NS	NS	Number of applications/ maximum seasonal rate and retreatment interval not specified in current label. **Label should be amended to limit use to only one application. If potatoes have been previously treated by aerosol fogger, a minimum 5 day retreatment interval is required before treating with the EC formulation.**
2749-519	6/28/96	2 lb/gal EC	CIPC 2 EC	0.0104 lb/1000 lb potato	NS	NS	NS	Number of applications/ maximum seasonal rate and retreatment interval not specified in current label. **Label should be amended to limit use to only one application. If potatoes have been previously treated by aerosol fogger, a minimum 5 day retreatment interval is required before treating with the EC formulation.**
Cerexagri, Inc.								

EPA Reg. No.	Label Acceptance Date	Formulation Class	Product Name	Current Label "Standard"[1] Application Rate (ai)	Current Label Max. Seasonal Application (ai)	Current Label Max. Number of Applications	Current Label Retreatment Interval	Recommended Label Amendments
2792-40	11/21/95	2 lb/gal EC	Decco 276 EC	0.0104 lb/1000 lb potato	NS	NS	NS	Number of applications/ maximum seasonal rate and retreatment interval not specified in current label. **Label should be amended to limit use to only one application. If potatoes have been previously treated by aerosol fogger, a minimum 5 day retreatment interval is required before treating with the EC formulation.**
2792-41	12/18/90	4.3 lb/gal RTU	Pennwalt Decco 273 Aerosol	0.017 lb/1000 lb potato	-	-	-	Cancellation Pending.
2792-69	8/8/95	7 lb/gal RTU	Decco 270 Aerosol	0.017 lb/1000 lb potato	NS (0.025 lb/1000 lb potato implied) [2]	NS	NS	The highest recommended rate listed is "145%" of the "standard" rate. A retreatment interval is not specified. **Label should be amended to specify a minimum retreatment interval of 3 months (90 days). A maximum of two treatments should be specified.**[3]
2792-70	8/8/95	9.66 lb/gal RTU	Decco 271 Aerosol	0.017 lb/1000 lb potato	NS (0.028 lb/1000 lb potato implied) [2]	NS	NS	The highest recommended rate listed is "165%" of the "standard" rate. A retreatment interval is not specified. **Label should be amended to specify a minimum retreatment interval of 3 months (90 days). A maximum of two treatments should be specified.**[3]

EPA Reg. No.	Label Acceptance Date	Formulation Class	Product Name	Current Label "Standard"[1] Application Rate (ai)	Current Label Max. Seasonal Application (ai)	Current Label Max. Number of Applications	Current Label Retreatment Interval	Recommended Label Amendments
SLNs								
ID830003			Sprout Nip 7A					cancelled
ME000004		9.66 lb/gal RTU [2749-520]	CIPC 98A	0.025 lb/1000 lb potato	NS (0.041 lb/1000 lb potato implied)[2]	NS	NS	The highest recommended rate listed is "165%" of the "standard" rate. A retreatment interval is not specified. **Label should be amended to specify a minimum retreatment interval of 3 months (90 days). A maximum of two treatments should be specified.**[3]

[1] See example below of the sliding scale table appearing on RTU labels where the "standard" application rate, or 100% treatment, is 0.017 lb/1000 lb potato (i.e. 1 lb ai/600 cwt).

TIME MONTHS	Storage Temperature				
	40°F	45°F	50°F	55°F	60°F
1	80%	90%	100%	110%	120%
2	85%	95%	105%	115%	125%
3	90%	100%	110%	120%	130%
4	95%	105%	115%	125%	135%

5	100%	110%	120%	130%	140%
6	105%	115%	125%	135%	145%
7	110%	120%	130%	140%	150%
8	115%	125%	135%	145%	155%
9	120%	130%	140%	150%	160%
10	125%	135%	145%	155%	165%

[2] The implied maximum rate is 165% of the standard rate, calculated to be 0.028 lb/1000 lb potato when standard rate is 0.017 lb/1000 lb potato (or 145% of standard rate, calculated to be 0.025 lb/1000 lb potato).

[3] RTU product labels state that "if potatoes are held in storage longer than originally anticipated, the potatoes may be retreated". Although the label language implies two treatments not to exceed 165% (or 145%) of the standard rate, the total number of treatments or maximum seasonal rate, is not clearly stated. The labels should clearly state a maximum of two treatments not to exceed a total rate of 165% (or 145%) of the standard rate. Also, a retreatment interval is not specified. The label should specify a minimum retreatment interval of 3 months (90 days) to reflect the minimum retreatment interval used in the residue field trials.

cc: RF, List A file, D.Drew, Cynthia Giles-Parker (RD), Gary Mullins (SRRD).
RDI: S. Knizner 4/8/02
D.Drew: CM2, Rm 821E, 305-6028